Pulmonary Arterial Hypertension Treated with Cardiosphere-Derived Allogeneic Stem Cells

Grant Award Details

Pulmonary Arterial Hypertension Treated with Cardiosphere-Derived Allogeneic Stem Cells

Grant Type: Clinical Trial Stage Projects

Grant Number: CLIN2-09444

Project Objective: Completion of a Phase 1a/1b Clinical Trial

Investigator:

Name:	Michael Lewis
Institution:	Cedars-Sinai Medical Center
Type:	PI

Disease Focus: Heart Disease, Pulmonary Hypertension, Vascular Disease

Human Stem Cell Use: Adult Stem Cell

Award Value: $7,354,772

Status: Active

Grant Application Details

Application Title: Pulmonary Arterial Hypertension Treated with Cardiosphere-Derived Allogeneic Stem Cells

Public Abstract:

Therapeutic Candidate or Device

CAP-1002

Indication

Patients with Pulmonary Arterial Hypertension (PAH)

Therapeutic Mechanism

CAP-1002's mechanism of action may result in reduced wall thickening of small blood vessels in the lung that are markedly narrowed/obstructed in PAH. The latter results in high resistance against which the right ventricle (RV) must pump in order to drive blood through the lungs. The RV eventually fails as a pump with ensuing heart failure/death. CAP- 1002 via effects on pulmonary vessels will also lighten the load on the RV. The above has been demonstrated in pre-clinical studies.

Unmet Medical Need

PAH is a progressive condition for which there is no cure. Even with substantial pharmacologic advances in the modern treatment era, survival still remains unacceptably poor. The administration of CDCs has the potential to reduce adverse arteriolar remodeling in PAH.

Project Objective

Completion of a Phase 1a & 1b clinical trial.

Major Proposed Activities

- To assess the maximum feasible dose and safety of CAP-1002 through a Phase 1a clinical trial in patients with PAH.
- To assess long term safety and exploratory efficacy outcomes of CAP-1002 through a randomized Phase 1b clinical trial in
  patients with PAH

Statement of Benefit to California:

Even with substantial pharmacologic advances in the modern treatment era, survival still remains unacceptably poor, as reported in large PAH registries. A novel, effective therapy that specifically addresses the underlying pathology responsible for PAH is sorely needed and may in addition offer a cost-effective adjunctive treatment that can reduce hospitalization and other costs of clinical worsening as occurs with with current therapies.

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